CHAPTER 1

The Evolving Challenge of Foodborne Illness Outbreak Response

CHAPTER SUMMARY POINTS

- Foodborne illness strikes tens of millions, hospitalizes more than 100,000, and kills an estimated 3,000 people in the United States each year.
- The U.S. diet has changed in response to numerous factors creating new food-safety challenges.
- Important advances in clinical laboratory techniques and public health approaches to detect and investigate clusters of illness are being used to better define the scope and nature of foodborne illness.
- Information systems and food-supply investigation techniques are developing to enhance our ability to trace contaminated foods, identify and control contamination sources, and remove contaminated food from circulation.
- Industry-driven and regulatory food-safety standards are being changed to better address risks identified by foodborne illness outbreak investigations to prevent similar outbreaks.

URLs in this chapter are valid as of July 11, 2019.

1.0 Introduction

Outbreaks of foodborne illness and their detection, investigation, and control are functions of several constantly changing factors. The U.S. diet has changed in response to public health recommendations; economics of food production and distribution; and the growing demands for convenience in food service, as well as diversity and freshness of foods in the marketplace. Important advances have been made in clinical laboratory techniques to diagnose foodborne illnesses and in public health approaches to detect and investigate clusters of illness. Information systems are developing to enhance our ability to trace contaminated food and eliminate it from circulation and to glean lessons learned from these investigations to prevent similar outbreaks. In addition, industry-driven and regulatory food-safety standards are being changed to better address risks identified by foodborne illness outbreak investigations to prevent similar outbreaks.

This chapter provides an overview of these ever-changing factors. Subsequent chapters detail specific approaches used by investigators.

1.1 The Burden of Foodborne Illness in the United States

1.1.1 In 2011, the Centers for Disease Control and Prevention (CDC) estimated that each year in the United States 47.8 million illnesses, resulting in 128,000 hospitalizations and 3,000 deaths, were attributable to contaminated food *(1, 2)*. Of these illnesses, 9.4 million are caused by 31 known agents of foodborne illness, and the remaining 38.4 million by unspecified agents. Tracking overall changes in the burden of foodborne illness from year to year is not currently possible, but trends are evident in known foodborne illnesses tracked by FoodNet (https://wwwn.cdc.gov/foodnetfast). Most notably, the incidence of *Escherichia coli* O157:H7 infections dropped from approximately 2.5 cases per 100,000 population during the mid-1990s to fewer than 1 case per 100,000 by the mid-2000s, accomplishing a goal of Healthy People 2010. Following early declines in the incidence of *Listeria* and *Campylobacter* infections, rates remained stable throughout the 2000s, whereas the incidence of *Vibrio* infections increased. Overall rates of *Salmonella* infections remained stable; the incidence of infection by serotypes Typhimurium and Heidelberg decreased; and infection by serotypes Enteritidis, Javiana, and the monophasic variant of Typhimurium, serotype I 4,[5],12:i:-, increased *(3)*.

Because not all illnesses caused by foodborne pathogens are individually reportable, recognition of other pathogen-specific trends relies on surveillance of foodborne illness outbreaks. CDC's National Outbreaks Reporting System (NORS) logged 20,854 outbreaks comprising 403,110 illnesses, 16,517 hospitalizations, and 392 deaths during 1998–2017 (https://wwwn.cdc.gov/norsdashboard/). Reporting of foodborne illness outbreaks caused by norovirus increased during 1998–2004, but since 2010, annual totals have varied little, hovering around 300 per year. A comparison of etiologies causing single-agent outbreaks during 2012–2017 with those during 2002–2011 showed that outbreaks caused by agents associated with poor food-holding practices in commercial food-service establishments decreased: *Bacillus cereus*, down from an average of 17 outbreaks per year to 10 per year; *Clostridium perfringens*, from 40 to 32 per year; scombroid or histamine, from 23 to 17 per year; and *Staphylococcus aureus*, from 27 to 12 per year. These changes most likely represent actual reductions in outbreak

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occurrence because the percentage of reported outbreaks for which no etiologic agent was identified dropped from 59% in 1998 to 23% in 2017 *(4)*.

1.1.2 In 2014, the U.S. Department of Agriculture's Economic Research Service (USDA–ERS) estimated the average annual economic burden of foodborne illness at $15.5 billion ***(5)***. USDA–ERS based this burden on cost estimates of foodborne illness caused by 15 major pathogens in the United States (Table 1.1). These 15 pathogens account for 95% of illnesses and deaths from foodborne illness acquired in the United States for which a pathogen was identified. These estimates include costs associated with medical treatment of acute and chronic illness, lost wages of persons who recovered, and costs associated with premature deaths.

Table 1.1. Estimated Annual Cost of Foodborne Illness, Estimated Total Foodborne Cases, and Average Cost per Case Identified, United States, 2013

PATHOGEN	TOTAL COST	ESTIMATED TOTAL FOODBORNE CASES	COST PER CASE
Vibrio vulnificus	$319,900,000	96	$3,332,000
Listeria monocytogenes	$2,834,400,000	1,591	$1,782,000
Toxoplasma gondii	$3,304,000,000	86,686	$38,100
Vibrio spp. (other noncholera)	$72,800,000	17,564	$8,100
Shiga toxin–producing *Escherichia coli* O157	$271,400,000	63,153	$4,300
Salmonella spp. (nontyphoidal)	$3,666,600,000	1,027,561	$3,600
Yersinia enterocolitica	$278,000,000	97,656	$2,900
Campylobacter spp.	$1,928,800,000	845,024	$2,300
Vibrio parahaemolyticus	$40,700,000	34,664	$1,200
Shigella (all species)	$138,000,000	131,254	$1,100
Cryptosporidium parvum	$51,800,000	57,616	$900
Norovirus	$2,255,800,000	5,461,731	$410
Clostridium perfringens	$342,700,000	965,958	$360
Non-O157 Shiga toxin–producing *E. coli*	$27,400,000	112,752	$240
Cyclospora cayetanensis	$2,300,000	11,407	$200

Source: U.S. Department of Agriculture. Cost estimates of foodborne illnesses. https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses

1.1 The Burden of Foodborne Illness in the United States

1.1.3 The impact of foodborne illness on the food industry varies greatly, and the costs seldom are limited to one company. This impact is evident when the distribution network of the food supply is considered. The impacts of recalls on the food industry are far-reaching, in some cases topping $10 million in direct costs.

Direct costs of recalls include notification of regulators, supply chain, and consumers; product retrieval, storage, and destruction; unsalable product; and the additional labor associated with these activities. These direct costs do not include litigation, increased regulatory compliance, and the impact to the company's market value and brand reputation.

The outbreak of *E. coli* O157:H7 infection associated with romaine lettuce grown in the Yuma, Arizona, growing region in April 2018 provides a good example of the indirect costs to the industry associated with lost sales and brand damage *(6)*. This outbreak sickened 210 people in 36 states. During the week that followed the initial news of the outbreak, sales of romaine lettuce fell 20% *(7)*. In addition, data from Nielsen also showed marked drops in sales of iceberg lettuce, red leaf lettuce, and endive. The impact of a second, although unrelated, outbreak of *E. coli* O157:H7 associated with romaine lettuce in November 2018 *(8)* was even more dramatic because CDC advised consumers to avoid eating romaine lettuce from any source in an effort to remove potentially contaminated romaine from commercial distribution channels.

With a more comprehensive accounting of potential costs, researchers at the Johns Hopkins Bloomberg School of Public Health suggested that the cost to a restaurant for a single foodborne illness outbreak can range from $4,000 to $2.6 million, depending on the pathogen, type of restaurant involved, and size of the outbreak. For example, a foodborne illness outbreak in which five people became sick in a fast food restaurant would result in costs of approximately $4,000 if there was no loss in revenue and no lawsuits, legal fees, or fines. In contrast, a single outbreak of listeriosis involving 250 persons in a fine dining restaurant could cost upwards of $2.6 million in lost sales, lawsuits, legal fees, fines, and higher insurance premiums *(9)*.

1.2 Growing Complexity of the Food Supply

U.S. food-consumption patterns change continuously. Changes in diets and food preferences have resulted in a greater demand for a broader variety of fruits, vegetables, and other foods. Moreover, Americans expect to consume these foods year-round, driving importation from areas of the world with the growing seasons necessary to meet U.S. demand. Meeting global supply-chain demands also has increased the complexity and logistics of how food is transported from farm to fork.

1.2.1 A major indicator of changing diets is the consumption of fresh fruits and vegetables. From 1996 to 2017, loss-adjusted per capita availability of fresh fruit increased 7% from 55 to 59 pounds *(10)*. Consumption of fresh vegetables increased only marginally from 68 to 70 pounds per person. During the same time, per capita consumption of chicken increased 30% from 40 to 52 pounds, whereas that of beef declined 17% from 49 to 41 pounds *(10)*. Within the arena of fresh produce, consumption of head lettuce declined 34% from 12 to 8 pounds per capita, whereas consumption of romaine and leaf

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lettuce doubled from 3 to 6 pounds per capita, and consumption of fresh spinach nearly tripled from 0.3 to 0.9 pounds per capita. Consumption of fresh berries also increased substantially. The general pattern of these dietary changes reflects public health recommendations toward healthier eating *(10)*.

The food industry has met this demand through routine importation of items once considered out of season or exotic. According to reports by USDA–ERS *(11)*, the proportion of imported fresh fruits increased from 39% in 1996 to 53% in 2016. Excluding bananas, for which there is no domestic production, the share of imported fruits increased from 16% to 38%. Similarly, the percentage of imported fresh vegetables increased from 14% to 31%. Although a high proportion of some fresh produce items, such as mango and papaya, always have been imported, an increasingly more conventional produce items are also imported. For example, the percentage of imported avocadoes increased from approximately 14% in 1996 to 89% in 2016, and that of blueberries increased from 24% to 57% during that same period *(11)*.

The safety of imported food products depends largely on the public health and food-safety systems of other countries. Recent analyses of foodborne illness outbreaks reported to CDC support the existence of food-safety problems in other countries. During 1996–2014, the number of confirmed foodborne illness outbreaks associated with imported foods increased from 3 per year to 18 per year. *Salmonella* and *Cyclospora* accounted for about one third of the outbreaks and 75% of cases, most due to contaminated produce from Latin America *(11)*.

1.2.2 Culinary preferences for undercooked or raw foods also contribute to more frequent infections and outbreaks caused by the microorganisms associated with these foods. These include classical outbreaks of Shiga toxin–producing *E. coli* (STEC), *Salmonella*, *Campylobacter,* and *Listeria* infections associated with raw milk and raw milk cheeses; *Salmonella* associated with raw tuna in sushi; and *Campylobacter* and *Salmonella* in minimally processed liver pates. A corresponding trend for raw pet foods made from meat and poultry products also has led to outbreaks among people from handling the raw pet food, exposure to ill animals, or environmental contamination in the household.

Foodborne illnesses also can be associated with ingestion of products not typically thought of as food. During 2017–2018, kratom, a tree leaf with stimulant and opioid properties, caused illness by a variety of *Salmonella* serotypes. Smoking marijuana caused an outbreak of salmonellosis in 1981 *(12)*; and a cannabis-associated toxidrome among four persons who attended the August 2014 Denver County Fair was associated with consumption of chocolate bars obtained at the "LoveAll" booth at the fair's "Pot Pavilion" *(13)*. The full legalization of cannabis products in at least nine other states and the District of Columbia since 2014 and associated sales of cannabis-infused edibles could lead to more foodborne illness outbreaks. However, no outbreaks from cannabis products were reported to NORS from 2015 to 2018.

1.2.3 Changes in how food is cultivated or raised, processed, and distributed and where, how, and by whom food is prepared also contribute to changing patterns of foodborne illness. The demand for processed and ready-to-eat foods has led to the industrialization of food production with increasingly intense agricultural practices and broadening distribution of food products. Changes in agricultural, processing, or packaging methods might facilitate bacterial contamination or growth. Large multistate STEC outbreaks associated with leafy green vegetables reflect the challenges of intensive

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animal and fresh produce production in a shared environment. The scale of these operations magnifies the impact of food-safety system failures, resulting in thousands of exposures and potential illnesses across multiple states, and even multiple countries.

Increasingly complex food-distribution systems span the globe. Products move from farm to fork through a network of farms, processors, manufacturers, packers, importers, brokers, storage facilities, distribution centers, and retail outlets. In some instances, food from a farm can change hands more than 10 times before it reaches a consumer. These complex supply chains are maintained by a wide variety of record-keeping systems; outbreak investigators charged with tracing foods back through the supply chain are left to decode these systems and piece together, step by step, how a food reached its final destination.

At the same time, a counter-trend promoting local food sources and small-scale farm-to table distribution networks (sometimes termed the "locavore movement" or "community-supported agriculture") has emerged. The number of small food producers and direct-to-consumer marketing avenues (e.g., farmer's markets, farm stands, farm-to-school programs, and "pick-your-own" operations) also has risen. According to national agriculture census data, from 1997 to 2017, direct sales of agricultural products to the public increased by 374%, compared with an increase of 93% for all agricultural sales. During the same period, the number of farms selling directly to consumers increased by 18%, compared with an 8% decrease in the total number of farms *(14)*. In addition, most states have "cottage food" laws, allowing small producers to cook, can, or pickle outside of licensed kitchens certain foods that are typically considered low-risk.

The effect of increased consumption of locally produced foods is yet to be determined, but the consequences of eating unsafe food apply to both small and large producers. For an individual, it is equally as bad to get STEC infection from farm-fresh strawberries harvested from a local field frequented by wild deer as it is to get STEC infection from romaine lettuce shipped hundreds of miles after contamination with runoff from a cattle feed lot. Although a small producer's limited distribution system might affect fewer people, implementing improved food-safety measures might be more challenging for the small producer. In addition, farm direct sales (i.e., farmers selling produce, eggs, and other foods they produced directly to retail customers, such as through farmers' markets and farm stands) are not included among food facilities in the 2011 Food Modernization and Safety Act (FMSA) *(15)*. In some states and local jurisdictions, these sales have been exempted from food-safety regulations that pertain to other food facilities.

By whom and where our food is prepared also plays a role in foodborne illness occurrence and outbreaks. Americans increasingly eat away from home, spending more than 50% of food dollars away from home, since 2010 *(16)*. During this period, there was considerable growth in limited service "fast casual" restaurants that featured more complex food handling than traditional fast-food restaurants. The increased number of meals eaten away from home most likely influenced the increase in foodborne illness. In an analysis of foodborne illness outbreaks reported to CDC during 2009–2017, 62% were associated with restaurants *(4, 17)*. In addition, studies of sporadic and outbreak-associated foodborne illness, including infection with STEC O157, *Salmonella enterica* serotypes Enteritidis and Typhimurium, and *Campylobacter jejuni* suggest that commercial food-service establishments, such as restaurants, play an important role in foodborne illness in the United States *(18)*.

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Finally, the growing e-commerce in delivery of groceries and restaurant food directly to consumers' homes provides foodborne illness investigators with opportunities for verifying food purchases and dates. Whether an increased risk for illness accompanies these means of food distribution remains to be determined.

1.3 Enhanced U.S. Foodborne Illness Surveillance Systems

A variety of surveillance systems have been developed to identify foodborne illness and detect outbreaks. Some systems focus on specific pathogens likely to be transmitted through food and have been used extensively for decades. More recently, new surveillance methods have emerged that provide data on food vehicles, settings, pathogens, contributing factors, and environmental antecedents. Effective surveillance to track cases of foodborne illness and outbreaks is critical to developing effective control strategies.

1.3.1 Changes in surveillance for human illness have affected how outbreaks are detected (Chapter 4) and investigated (Chapter 5). All states and territories have legal requirements for the reporting of certain illnesses and conditions, including illnesses likely to be foodborne (e.g., salmonellosis, campylobacteriosis, and STEC infection), by healthcare providers and laboratories to the local, state, or territorial public health agency (Chapter 2). Local and state agencies also receive and respond to complaints of illness directly from the public. The adoption of new testing methods in clinical and public health laboratories, as well as improved information management systems and social media, are transforming surveillance activities.

- Molecular subtyping by public health laboratories has been the basis for national pathogen-specific surveillance since the initiation of PulseNet in 1996. The use of pulsed-field gel electrophoresis (PFGE) increased the ability to link isolates from distant locations and thereby to infer epidemiologic relatedness; PFGE revolutionized the detection and investigation of foodborne illness outbreaks and led to prevention of illnesses. However, PFGE provided limited information about the organism itself. Rapid bacterial sequencing technology and the informatics tools needed to accommodate whole-genome sequencing (WGS) have been developed and in 2019 rapidly deployed to public health laboratories across the United States. On July 15, 2019, WGS replaced PFGE as the primary molecular subtyping tool for pathogen-specific surveillance.
- Concurrent with the development of WGS to improve molecular subtyping, clinical laboratories have moved away from traditional fecal culture in favor of culture-independent diagnostic tests (CIDTs). These methods can rapidly identify pathogens and expedite treatment decisions, but they do not yield the bacterial isolates required by public health officials. Many public health jurisdictions require submission of CIDT-positive specimens for subsequent culture and subtyping—but this shifts the burden of isolation from the clinical laboratory to the public health laboratory and delays cluster recognition. Conversely, CIDTs may be more sensitive and offer the prospect of detecting pathogens (e.g., enterotoxigenic *E. coli*) that may elude detection by culture. FoodNet, the 10-site active surveillance program for infections often transmitted through foods, has increased collection of data on use of CIDTs and on the frequency and results of reflex cultures.

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- Newer technologies are likely to lead to recognition of more clusters and reduced cluster sizes than with PFGE. They also take longer, delaying cluster recognition by this means.
- Improved epidemiologic investigation practices have been developed. These include the standardization of common data elements for interviewing case-patients, use of standardized hypothesis-generating questionnaires, increased use of consumer product purchase (e.g., "shopper card") data, aggregation of case-patient exposures and comparison with population reference standards, and improved subcluster investigation and informational traceback methods to improve the specificity of exposure assessments.
- The principles of foodborne illness complaint surveillance are being standardized (Chapter 4). The value of using electronic databases to review and analyze complaints and to link complaints with pathogen-specific surveillance systems has been demonstrated. Numerous social media platforms have been evaluated to assess their potential utility to enhance conventional complaint surveillance. To the extent these can facilitate linking illnesses with exposure, rather than just reinforcing the "last meal eaten" bias, they may warrant attention from public health agencies.
- Standards and procedures for outbreak reporting have been developed for NORS. NORS supports outbreak reporting from state, local, and territorial health departments in the United States. NORS Dashboard is a public-facing, web-based tool containing limited and cleaned NORS data that can be filtered using an interactive interface that produces summary data, statistics, and a variety of graphs based on user preferences (https://wwwn.cdc.gov/norsdashboard). CDC, USDA's Food Safety and Inspection Service (FSIS), Food and Drug Administration (FDA), and other investigating agencies analyze these data to improve understanding of the impact of foodborne illness outbreaks on human health and of the pathogens, foods, and settings involved in these outbreaks.
- Specialized surveillance networks have been developed for specific pathogens. For example, CaliciNet is a norovirus outbreak surveillance network of local, state, and federal public health laboratories. Network partners perform viral sequencing and upload sequences into CaliciNet to monitor circulating strains, and identify newly emerging norovirus strains. CaliciNet outbreak lab data are linked to matching outbreak data in NORS. CryptoNet, the first U.S. national molecular tracking system for a parasitic infection, was formally launched in 2015 to collect specimens and to characterize the molecular epidemiology of infection by *Cryptosporidium* spp., only some of which are pathogenic for humans but which are typically indistinguishable morphologically.

1.3.2 Surveillance for food-preparation hazards and environmental assessments of outbreaks have been developed to identify root causes (Chapter 5) and improve preventive controls (Chapter 6). Routine food-safety inspections are conducted for all licensed food-service establishments by approximately 3,000 local and 75 state and territorial agencies. Although traditionally conducted to ensure that food-service establishments were operating within the provisions of state food codes, many of which are adopted from the FDA Model Food Code *(19)*, inspection results are being increasingly displayed at the point of service or online to provide information to consumers about potential food-safety risks. A growing body of evidence suggests that such public disclosure of inspection results might improve restaurant

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inspection results and reduce the risk for illness transmission to patrons.

- To standardize assessment of retail food risk factors, FDA initiated the Retail Food Risk Factor Study to measure practices and behaviors commonly identified as contributing factors in foodborne illness outbreaks *(20)*. Data from the initial study, collected during 1998, 2003, and 2008, documented progress toward the goal of reducing contributing factors (https://www.cdc.gov/nceh/ehs/nears/cf-definitions.htm) at retail establishments: five of the nine facility types showed a statistically significant improvement in compliance for all 42 contributing factors during the study period. A second round of the Retail Food Study was initiated in 2013 to assess food-protection manager certification and food-safety management systems. One important finding from the study was that fewer food-safety items were out of compliance in restaurants having well-developed and documented food-safety management systems *(20)*.
- The Environmental Health Specialists Network (EHS-Net) of environmental health specialists and epidemiologists from local and state health departments, FDA, FSIS, USDA's Food and Nutrition Service, and CDC developed the National Environmental Assessment Reporting System (NEARS) to systematically monitor and evaluate root causes of foodborne illness outbreaks, including contributing risk factors and environmental antecedents. This system is cross-referenced with NORS and collects information from detailed environmental assessments on factors contributing to the outbreak and the underlying conditions that led to it. The information collected through NEARS can inform hypothesis generation about antecedents to foodborne illness outbreaks and strengthen the ability of food-control authorities to formulate and evaluate the effectiveness of food-safety actions.

1.3.3 The food supply and associated environments are tested by local, state, and federal regulatory officials and the food industry. Food testing is a tool used to assess whether an establishment's food-safety system is functioning adequately to address hazards in food production and manufacturing and prevent foodborne illnesses. Food and environmental testing data, including molecular subtyping data, can be used to inform hypothesis generation during outbreaks. Food testing data also can be used to estimate the fraction of selected foodborne illnesses caused by specific food sources, to assess changes in food contamination over time, and to assess the success of regulatory measures. Foodborne pathogens of interest that are isolated from food or from animal or environmental sources during various government testing programs are being characterized by WGS and the sequence data added to FDA's GenomeTrakr BioProjects housed at NIH NCBI, where they can be compared with data from human isolates directly on NCBI Pathogen Browser and/or in the CDC-PulseNet National Database. No formal framework exists to link industrywide testing to public health surveillance data. Mechanisms have been discussed that would provide access to aggregated, or blinded industry data to avoid regulatory penalties to individual companies.

To ensure technical competence and the ability to generate reliable data, food testing laboratories within FDA and FSIS maintain accreditation in the International Organization for Standardization/International Electrotechnical Commission 17025 standard—the main international standard used by testing and calibration laboratories. Additionally, FDA is leading an effort to bring state human and animal food testing laboratories into International Organization for Standardization/International Electrotechnical Commission 17025 accreditation to enhance efforts to protect the food supply. Data

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generated by accredited laboratories will be made available for consideration during FDA enforcement actions, as well as for surveillance purposes and during local, state, or federal response to foodborne illness outbreaks.

Laboratory accreditation also will assist state manufactured food-regulatory programs in achieving conformance with the Manufactured Food Regulatory Program Standards.

1.4 Foodborne Illness Outbreak Response and System Change

1.4.1 Although foodborne illness surveillance and response are rooted in individual states' laws, the growing trend in multistate outbreaks associated with widely distributed foods requires increasing standardization of methods, integration of activities, and federal support and oversight. In response to the emergence of *E. coli* O157:H7 and other foodborne pathogens during the 1990s, CDC developed the active surveillance network FoodNet, with funding assistance from FSIS and FDA, to conduct comprehensive surveillance of diagnosed illnesses within defined populations to assess and monitor trends in the burden of illness associated with specific agents. Simultaneously, CDC established the national molecular subtyping network PulseNet to improve laboratory-based surveillance for bacterial pathogens routinely detected by clinical laboratories. PulseNet increased detection of multistate outbreaks, and FoodNet provided a framework to interpret the impact of food system changes in response to improved outbreak detection and regulatory activity.

In 2005, CIFOR was established to identify barriers to effective surveillance and investigation of foodborne illnesses and outbreaks. One of the first CIFOR projects was to develop guidelines for outbreak detection and response. The First Edition of the CIFOR Guidelines, published in 2009, established model practices for foodborne disease surveillance at local and state levels, with specific reference to coordination of multijurisdictional outbreaks investigations and development of performance indicators to measure the effectiveness of surveillance activities. The Second Edition of the Guidelines was published in 2014.

During this time, CDC began providing dedicated funding to support state-level foodborne illness outbreak response through Epidemiology and Laboratory Capacity cooperative agreements. This led to development of several CDC programs: OutbreakNet, CDC's Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE), and the Integrated Food Safety Centers of Excellence and OutbreakNet Enhanced (OBNE). The CDC Integrated Food Safety Centers of Excellence were created by FSMA. These programs are intended to work together to enhance the development and evaluation of foodborne illness surveillance and outbreak response activities across the United States.

In conjunction with CDC's investments in the performance of public health agencies, FDA has used additional resources provided by FSMA to develop a network of Rapid Response Teams (RRT) to enhance coordination between public health and food-regulatory agencies at the state level and formed a Coordinated Outbreak Response and Evaluation (CORE) Network to centralize coordination of outbreak response activities within FDA. FSIS has developed parallel outbreak response capacity (Chapter 3).

1.4 Foodborne Illness Outbreak Response and System Change

With a stated goal of building an Integrated Food Safety System, FDA established the Partnership for Food Protection in 2008, bringing together local, state, territorial, tribal, and federal representatives with expertise in food; feed; epidemiology; laboratory; and animal, environmental, and public health. The Partnership for Food Protection (PFP) brings the collective expertise of the above stakeholders to work on projects that enhance human and animal food safety in the United States.

Coordination of activities on the federal level is accomplished through mutual liaisons between agencies, and joint participation in the Intergovernment Food Safety Analytics Collaboration (IFSAC) which seeks to improve the use of outbreak surveillance in foodborne illness attribution models and thus better guide food-safety regulation. Chapter 3 details the agencies currently involved in foodborne illness outbreak response, along with their respective roles and responsibilities. Issues posed in the response to multijurisdictional outbreaks are discussed in Chapter 7.

1.4.2 Food-safety standards are changing to better control food-safety risks identified by foodborne illness outbreak investigations. Both industry-driven standards (e.g., from the Global Food Safety Initiative, https://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html) and government-driven regulatory requirements are being updated to identify and manage food-safety hazards more rapidly. Examples of noteworthy regulatory changes in the United States include

- The 2011 FSMA—the first major reform of the FDA's food-safety authority since the 1938 enactment of the Food, Drug, and Cosmetic Act. Since the Second Edition of the CIFOR Guidelines, some key provisions of FSMA have been rolled out in seven federal regulations (Chapter 2), which provide FDA with additional legal authorities and resources to strengthen food-safety systems. They enable FDA and its food-safety partners, to focus on preventing food-safety problems and to address food-safety risks more rapidly when they are identified. FSMA and its associated regulations grant FDA substantial new authority to protect food all along the farm-to-fork line, covering preventive controls, inspections, laboratory testing, product tracing, mandatory recall authority, importer accountability, authority to deny entry to the U.S. market, state and local capacity building, and other areas.
- Since enactment of its Pathogen Reduction, Hazard Analysis and Critical Control Point Systems rule to reduce risks associated with meat and poultry in 1996, FSIS has continued to address food-safety hazards. In 2011, FSIS established raw poultry performance standards for *Campylobacter* and updated existing ones for *Salmonella*. In 2012, FSIS added six non-O157 STEC serogroups as "adulterants" in raw beef. In 2015, after agency investigators noted they often were impeded in efforts to trace ground beef to its source during outbreak investigations and in response to STEC-positive sample results, FSIS required its regulated establishments and retail stores to maintain detailed records to identify all ground-beef source materials.

In summary, the foods we eat and the processes by which they are produced, distributed, and prepared; the means for diagnosing illness and detecting outbreaks; the methods whereby outbreaks are investigated; and the response of government and private partners are always changing. The following chapters provide updated guidance to responders with these changes in mind. The final chapter (Chapter 8) provides and references metrics for evaluating an agency's progress toward optimizing its response to foodborne illness outbreaks.

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